

REMARKS

The Office Action of February 16, 2012 has been received and carefully reviewed. It is submitted that, by this Amendment, all bases of rejection and objection are traversed and overcome. Upon entry of this Amendment, claims 1-10, 19-24, and 26-33 are pending in the application. Claims 1-10 and 19-22 have been withdrawn. Reconsideration of the claims is respectfully requested.

The specification stand objected to for failing to include the application number of the referenced application and for including hyperlinks. Applicants have revised the specification herein to address these issues. As such, it is submitted that the objections to the specification have been overcome.

Claims 23, 24 and 26-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tokie (U.S. Patent No. 6,513,897, referred to herein as "Tokie") in view of Strickley (Pharmaceutical Research, Vol. 21, No. 2, pages 201-230, February 200, referred to herein as "Strickley") and Johnson, et al. (U.S. Patent No. 6,983,636, referred to herein as "Johnson").

Applicants again disagree that one skilled in the art would combine Strickley with Tokie, alone or in combination with Johnson. Strickley is not at all related to inkjet printing. Tokie does mention, almost in passing, that his inkjet fluid material may include additives, such as pharmaceutical compounds (Col. 9, lines 44-55). However, Tokie provides **no examples** of pharmaceutical compounds that are dispensable from thermal inkjet printers. Strickley does not provide this deficiency. Rather, Strickley teaches excipients that may be used to solubilize drugs in oral and injectable (not inkjet printable) dosage forms (Introduction, page 201). Strickley teaches very specific combinations of molecules (i.e., drugs) and suitable excipients for the respective molecules (see Table 1) for use in oral or injectable dosage forms. Strickley does not teach or suggest that these dosage forms are then inkjet printable. As such, the Applicants again fail to see why one skilled in the art would combine Tokie with Strickley.

In addition, the Office implies that Strickley teaches the claimed surface tension because the reference teaches both digoxin as a water insoluble drug and dimethylsulfoxide (DMSO) as an excipient, and digoxin and DMSO is an example of the Applicants' pharmaceutical solution. However, Strickley does **not** teach or suggest the use of DMSO *with* digoxin, at least in part because the reference never teaches that DMSO is an excipient for digoxin. According to the teachings of Strickley, excipients for digoxin include a combination of PEG 400, ethanol 8%, and propylene glycol, or a combination of ethanol 10%, methyl paraben 0.1%, citric acid, flavor, propylene glycol, sodium phosphate, and sucrose (see Table 1, page 204). The left column on page 208 of Strickley states "[d]igoxin is solubilized in a cosolvent mixture of propylene glycol, PEG 400, and 8% ethanol in 200-µg soft gelatin capsules." The bottom of the left column continuing on the top of the right column of page 208 of Strickley states "[d]igoxin, a non-ionizable cardiotonic glycoside, is practically insoluble in water and is solubilized in propylene glycol, 10% ethanol, flavor, sweetener, preservative, and buffers to 50-µg/ml in Lanoxin Elixir Pediatric...." When discussing DMSO, Strickley states that it is an excipient for leuprolide acetate (page 225, left column). The Applicants fail to see where Strickley actually teaches or even suggests using DMSO in combination with digoxin. Since Strickley fails to teach or even suggest the combination of DMSO and digoxin, it is submitted that one skilled in the art would not be led to select random drug and excipient combinations from Strickley to arrive at a pharmaceutical solution that is to be dispensed from a thermal fluid ejection device and that has the surface tension set forth in the Applicants' independent claim 23. As noted by the Office on page 6 of the instant Office Action, both Tokie and Johnson are silent regarding the fluid surface tension. Since Strickley does not supply this deficiency, it is submitted that the combination of the references fails to render obvious Applicants' claim 23.

Furthermore, the Office notes that Tokie and Johnson are silent regarding the Applicants' recited viscosity. In fact, Tokie provides a specific viscosity (Col. 9, lines 12-16), which is above the range set forth in Applicants' independent claim 23. It is

submitted that one skilled in the art would not be led to randomly select pharmaceuticals and solvents that are outside of the viscosity range specifically provided by Tokie. The Office points out that the Applicants' claim 26 recites digoxin and DMSO. The Office concludes that Strickley's teaching of digoxin and DMSO would lead to the Applicants' viscosity range. However, as noted above, Strickley never actually teaches the use of digoxin with DMSO. Rather, Strickley teaches a list of excipients for digoxin, and DMSO is not on that list. There is no guidance provided by Strickley to suggest that random pharmaceutical compositions from his reference that are outside of Tokie's viscosity range can successfully be jetted using Tokie's device. Furthermore, Strickley teaches that surfactants may be added, which may further alter the viscosity. Therefore, it is submitted that one would not "necessarily" or even likely achieve the Applicants' pharmaceutical solution having the recited viscosity in view of the teachings of the cited references.

For all the reasons stated above, it is submitted that Applicants' invention as defined in independent claim 23, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

Claims 23, 24 and 26-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tokie in view of Johnson and further in view of Winnik et al. (U.S. Patent No. 5,541,633, referred to herein as "Winnik").

The combination of references fails to teach or even suggest the Applicants' pharmaceutical solution as defined in independent claim 23, which includes an active pharmaceutical ingredient dissolved in a vehicle, where the active pharmaceutical ingredient is any of digoxin, prednisolone, sulfamethoxazole, or reserpine. Support for this claim recitation may be found in the application as filed, at least at page 9, lines 7-9.

These active pharmaceutical ingredients are not taught or suggested by the cited references. As noted above, Tokie mentions in one sentence that suitable additives for his fluid composition may include pharmaceutical compounds, but he

provides no examples of these “pharmaceutical compounds”. Johnson and Winnik do not teach or suggest pharmaceutical solutions at all, and thus do not supply the deficiencies of Tokie. Guidance for selecting pharmaceutical compounds that can be thermally inkjet printed are not provided by any of the references, and thus it is submitted that the cited references fail to teach, suggest or otherwise render obvious the Applicants’ invention as defined in independent claim 23.

For all the reasons stated above, it is submitted that Applicants’ invention as defined in independent claim 23, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

Claims 26 and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tokie in view of Johnson and Winnik, and further in view of Strickley.

Applicants reiterate the arguments set forth hereinabove, and submit that one skilled in the art would not be led to combine Strickley with Tokie, either alone or in combination with Johnson and Winnik. Furthermore, it is again noted that Strickley does not actually teach the combination of digoxin with DMSO. Strickley teaches very specific excipients for digoxin, and DMSO is not one of them. DMSO is taught as an excipient for other drugs. Therefore, Strickley does not supply the deficiencies of Tokie, Johnson and Winnik regarding the specific pharmaceutical solution set forth in Applicants’ claims 26 and 33.

It is submitted that the absence of a reply to a specific rejection, issue or comment in the instant Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this amendment should be construed as an intent to concede any issue with regard to any claim, and the amendment of any claim does not signify concession of unpatentability of the claim prior to its amendment.

In summary, claims 1-10, 19-24, and 26-33 are pending in the application. In view of the foregoing arguments, all pending claims are believed to be in condition for

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allowance, and such action is respectfully requested. Therefore, this response is believed to be a complete response to the Office Action, and further and favorable consideration is respectfully requested.

If the Examiner believes it would expedite prosecution of the above-identified application, the Examiner is cordially invited to contact the undersigned attorney at the below-listed telephone number.

Respectfully submitted,

DIERKER & ASSOCIATES, P.C.

/Julia Church Dierker/

Julia Church Dierker
Attorney for Applicant
Registration No. 33368
(248) 649-9900, ext. 25
juliad@troypatent.com

3331 West Big Beaver Rd., Suite 109
Troy, Michigan 48084-2813
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JCD/JRK/hmp